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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,506	08/10/2001	Oxana Ibraghimov-Beskrovnyaya	126881201600	8221

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[REDACTED] EXAMINER

HADDAD, MAHER M

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1644

DATE MAILED: 09/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/830,506	IBRAGIMOV-BESKROVNAYA E AL.
	Examiner Maher M. Haddad	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 April 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-22,24-27 and 29 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 23 and 28 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 01 April 2003 is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) Interview Summary (PTO-413) Paper No(s). _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 4/1/03 (Paper No. 14), is acknowledged.
2. Claims 1-29 are pending.
3. Claims 1-22, 24-27 and 29 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.
4. Claims 23, and 28 are under consideration in the instant application.

5. In view of the amendment filed on 4/1/03 (Paper No. 14), only the following rejections remained.
6. The following is a quotation of the second paragraph of 35 U.S.C. 112.
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 23 and 28 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- A) The term "suitable tissue" recited in claim 23, line 1 and claim 28, line 2 is ambiguous and unclear and the metes and bounds of the claimed "suitable" is not defined.

Applicant argues in conjunction with case law that the rejection on the bases that the term "suitable tissue" should be read in light of the specification. Applicant asserts that the specification on page 42, lines 6-9 and page 17, lines 18-24, page 24, lines 13-16 and page 47, lines 20-28.

While the specification on page 17, line 24, discloses the kidney, liver, brain and neuronal tissues to express PKD1 polypeptide, however the metes and bounds of the claimed "suitable tissue" is unknown. It is unclear what specific tissue propriety is claimed.

It is suggested that applicant further defined suitable tissue as disclosed on page 47, lines 8-9 or recites specific tissue as disclosed on page 17, line 24.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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9. Claims 23 and 28 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for enhancing cell-cell adhesion in a polycystin expressing tissue, comprising delivering to the tissue an antibody against polycystin in vitro, does not reasonably provide enablement for a method for modulating cell-cell adhesion in any suitable tissue, comprising delivering to the tissue any agent that modulates the biding of polycystin in the tissue, wherein the modulation of cell-cell or cell-matrix adhesion is promotion or enhancement of cell-cell or cell-matrix adhesion in a suitable cell or tissue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for the same reasons set forth in the previous Office Action, paper No. 11, mailed 11/20/02.

Applicant traverses the rejection on the basis that the Office has failed to meet its initial burden of providing a prima facie case to support the rejection. Applicant recited *In re Marzocchi* to support his position and the Enablement Training Manual.

However, while references should be supplied if possible to support a prima facie case of lack of enablement, but are not always required. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). However, specific technical reasons are always required. Again as mentioned in the previous Office action, the specification fails to provide sufficient direction or objective evidence as to how to make and to how to use any agent which enhances cell-cell adhesion for the number of possibilities associated with the myriad of direct and indirect effects associated with various "agents" and, in turn, as to whether such a desired effect can be achieved or predicted, as encompassed by the claims.

Applicant further argues that the Office has failed to provide any technical or scientific reasoning why Applicants' disclosure fails to enable claims 23 and 28. Applicant asserts that the disclosure enable more than antibodies to polycystin.

However, the specification fails to provide a representative number of structurally related agents. The artisan would not know the identity of a reasonable number of representative agents falling within the scope of the instant claims and consequently would not have known how to make them.

Applicant argues that the Office has failed to provide any evidence why evidence of enhancement of cell-cell adhesion using the disclosed method to modulate cell adhesion would not be predictive of in vivo efficacy. Absent evidence to the contrary.

Again, *in re Fisher*, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Since no animal was used as model system to enhance cell-cell adhesion. It is not clear that reliance on in vitro model to disrupt cell-cell adhesion accurately reflects the relative mammal efficacy of the claimed therapeutic strategy. The specification does not adequately teach how to effectively reach any therapeutic endpoint in mammals by administrating the therapeutic the antibody against

polycystin. The specification does not teach how to extrapolate data obtained from in vitro model of disrupt cell-cell adhesion studies to the development of effective in vivo therapeutic treatment, commensurate in scope with the claimed invention. Therefore, it is not clear that the skilled artisan could predict the efficacy of the antibodies for enhancement of cell-cell adhesion exemplified in the specification.

Further, in view of the lack of predictability of the art to which the invention pertains the lack of established clinical protocols for effective cell adhesion-based therapies, undue experimentation would be required to practice the claimed methods with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed methods and absent working examples providing evidence which is reasonably predictive that the claimed methods are effective for the promotion or enhancement of cell-cell or cell-matrix adhesion. Furthermore, there is insufficient guidance and direction in the specification for diseases or conditions that would be targeted with anti-polycystin antibody.

In view of the absence of a specific and detailed description in Applicant's specification of how to effectively use the methods as claimed, and absence of working examples providing evidence which is reasonably predictive that the claimed methods are effective for in vivo use, and the lack of predictability in the art at the time the invention was made, an undue amount of experimentation would be required to practice the claimed methods with a reasonable expectation of success.

10. Claims 23 and 28 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the same reasons set forth in the previous Office Action, paper No. 11, mailed 11/20/02.

Applicant is in possession of a method for enhancing cell-cell adhesion in a polycystin expressing tissue, comprising delivering to the tissue an antibody against polycystin *in vitro*.

Applicant is not in possession of a method for modulating cell-cell adhesion in any suitable tissue, comprising delivering to the tissue any agent that modulates the bidding of polycystin in the tissue, wherein the modulation of cell-cell or cell-matrix adhesion is promotion or enhancement of cell-cell or cell-matrix adhesion in a suitable cell or tissue.

It appears that applicant included the written description arguments with the enablement argument. Therefore Examiner rebuttal is the same as above.

11. No claim is allowed.

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12. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad, whose telephone number is (703) 306-3472. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9307.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
September 8, 2003


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